Independence and mobility after infrainguinal lower limb bypass surgery for critical limb ischemia

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Background: **Critical limb ischemia (CLI) is a common condition associated with high levels of morbidity and mortality. Most work to date has focused on surgeon-oriented outcomes such as patency, but there is increasing interest in patient-oriented outcomes such as mobility and independence.**

Objective: **This study was conducted to determine the effect of infrainguinal lower limb bypass surgery (LLBS) on postoperative mobility in a United Kingdom tertiary vascular surgery unit and to investigate causes and consequences of poor postoperative mobility.**

Methods: **We collected data on all patients undergoing LLBS for CLI at our institution during a 3-year period and analyzed potential factors that correlated with poor postoperative mobility.**

Results: **During the study period, 93 index LLBS procedures were performed for patients with CLI. Median length of stay was 11 days (interquartile range, 11 days). The 12-month rates of graft patency, major amputation, and mortality were 75%, 9%, and 6%, respectively. Rates of dependence increased fourfold during the first postoperative year, from 5% preoperatively to 21% at 12 months. Predictors of poor postoperative mobility were female sex (P = .04) and poor postoperative mobility (P < .001), initially and at the 12-month follow-up. Patients with poor postoperative mobility had significantly prolonged hospital length of stay (15 vs 8 days; P < .001).**

Conclusions: **Patients undergoing LLBS for CLI suffer significantly impaired postoperative mobility, and this is associated with prolonged hospital stay, irrespective of successful revascularization. Further work is needed to better predict patients who will benefit from revascularization and in whom a nonoperative strategy is optimal. (J Vasc Surg 2014;59:983-7.)**

Critical limb ischemia (CLI) is defined as the presence of chronic ischemic rest pain, ulcers, or gangrene attributable to objectively proven arterial disease.[1] Recent estimates suggest that up to 1000 new cases of CLI per 1 million population are diagnosed every year in Europe and North America and that CLI is associated with high short-term and longer-term mortality rates.[1,2] Revascularization is required to prevent ultimate limb loss, and although there is an increasing vogue toward endovascular intervention, there is strong support for the role of infrainguinal lower limb bypass surgery (LLBS).[3,4]

Traditional measures of the success of LLBS have focused on indicators of technical success, such as graft patency, limb salvage, or ankle-brachial pressure index, because these are easily measured, objective measures. There has been a shift toward more patient-centered outcome measures to determine the "success" of intervention.[5] This is particularly important in conditions such as CLI, where rates of comorbid disease are high.[6] Such measures include quality of life (QOL) analysis with well-validated disease-specific QOL tools available for lower limb ischemia.[7] Chetter et al[8] were one of the first groups to highlight that graft patency equates to an immediate and lasting improvement in health-related QOL, but such infrainguinal arterial reconstruction is itself a potentially morbid procedure, and graft patency itself does not guarantee clinical improvement.[9] Other important patient-specific outcomes include residential status and mobility reflecting functional outcome. Reflecting this change of focus, the recently published Comprehensive Risk After Bypass (CRAB)[10] score is the first risk-scoring tool for LLBS to include functional status within its scoring algorithm.

No study has yet presented data related to contemporary practice within the United Kingdom (UK) health care system. Thus, this study aimed to determine the effect of infrainguinal LLBS on postoperative mobility and to investigate causes and consequences of poor postoperative mobility. We also provide the first external validation of the CRAB score as a predictor of outcomes in LLBS.

METHODS

Patients. Data were collected retrospectively on all patients undergoing infrainguinal LLBS for CLI at a tertiary vascular surgical unit from January 1, 2009, to January 31, 2012. Paper and electronic notes were interrogated in all cases where these were available. One set of paper notes could not be retrieved, so this

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patient was excluded from the analysis for all quantities that could not be reliably extracted from the electronic records. The hospital electronic medical records system is linked to the Office for National Statistics for recording mortality. Information was collected on basic demographics, basic hematologic and biochemical measurements, comorbidities, presence or absence of tissue loss, bypass origin and target vessels, graft type, hospital length of stay, and ambulatory status on admission to and discharge from the hospital. Presurgical data were then used to calculate Finnvasc, Project of Ex-Vivo graft Engineering via Transfection III (PREVENT III), Revised Cardiac Risk Index (RCRI), and CRAB scores to allow risk prediction of postoperative outcomes.[10-13] Details of these scores are given in Supplementary Table I (online only).

A cohort of patients underwent multiple bypass procedures. We felt that if subsequent procedures were ≤12 months of the previous bypass, the patient might not have recovered from the previous operation, and thus determining the baseline for comparisons would be difficult. As such, a "repeat" operation on the ipsilateral limb or on the contralateral limb was deemed to be a new "episode" only if the previous LLBS was performed at least 1 year previously. Repeat operations within 1 year of the previous LLBS were excluded. Graft patency was determined using arterial duplex scanning.

Definitions of mobility. For the purposes of analysis, mobility was stratified into three groups: dependent patients, who were bed-bound or wheelchair-bound; aided patients, who were ambulant but with significant dependence on mobility aids, including those who mobilized with a prosthesis, walking frame, or one or more elbow crutches; and independent patients, defined as those fully independent from mobility aids or requiring no more than a walking stick for assistance.

Physiotherapists determined mobility on admission and discharge. Vascular specialist nurses, physiotherapists, or surgeons determined mobility at routine 12-month follow-up assessments. No home visits were made.

Statistical analysis. The primary outcome was independent mobility 1 year after surgical revascularization. Secondary outcomes were graft failure and mortality in-hospital and 12 months after LLBS, and hospital length of stay during the index admission. Graft failure was defined as occlusion of the graft on duplex ultrasound imaging or contrast computed tomography (CT). Nonparametric analysis was performed in the R 2.15.2 statistical software (The R Foundation for Statistical Computing, http://www.r-project.org/foundation/)[14] to assess for univariate predictors of poor postoperative mobility using the Fisher exact test for categoric variables and the Mann-Whitney *U* test for continuous variables. Multivariate analysis was not performed.

RESULTS

One hundred procedures were performed on 90 patients (64 men) with CLI, with 93 bypasses being considered as distinct index "episodes." The overall mean ± standard deviation age was 70 ± 11 years. Of the 93 bypasses performed, 51 were performed electively, 53 were for tissue loss (31 with gangrene and 22 with ulceration only), and the distal bypass target vessel in 20 was the above-knee popliteal artery. Further graft-specific details are given in Supplementary Tables II and III (online only). Six patients underwent repeated LLBS during the 1-year follow-up period. Further details of the lesions treated and the reasons for choosing LLBS rather than an endovascular intervention are given in Supplementary Tables IV and V (online only).

The median hospital length of stay was 11 days (interquartile range, 11 days). No patients died before hospital discharge or ≤30 days of surgery. Three patients, who underwent three bypass procedures, were lost to follow-up ≤12 months. The 1-year mortality rate was 6% (five patients). Two patients progressed to major amputation during their index admission. At 12 months, 25% of grafts had occluded, with 9% of patients having progressed to major amputation. Minor amputations were required in 19 patients, comprising 17 digital amputations and two forefoot amputations. Within the first year of follow-up, 26 patients underwent an endovascular intervention aimed at maintaining graft patency. Five of these grafts subsequently failed despite these interventions. Further details of reinterventions are given in Table I. Three patients required contralateral LLBS during the first year of follow-up.

Mobility. On admission, 68 of 93 patients were classified as independent, 21 as aided, and four were dependent. At discharge, 51 patients were independent, 35 were aided, and seven were dependent. Data were available for 82 patients at 12 months, at which point 52 patients were independent, 13 were aided, and 17 were dependent. Further breakdown of changes in mobility over the first year of follow-up are given in Table II and the Fig. The

Table I. Ipsilateral reinterventions in the first 12 months after lower limb bypass surgery (LLBS)

Intervention	*Grafts, No.*
No further intervention	62
Re-look for bleeding	3
Thrombectomy/lysis	8
Upstream/downstream angioplasty	11
Graft angioplasty/patch plasty	15
Redo bypass	4

Table II. Mobility of the cohort preoperatively and during the postoperative period up to 1 year

Variable	*No.*	*Independent, %*	*Aided, %*	*Dependent, %*
Admission	93	72	23	5
Discharge	93	55	38	7
12 months	82	63	16	21

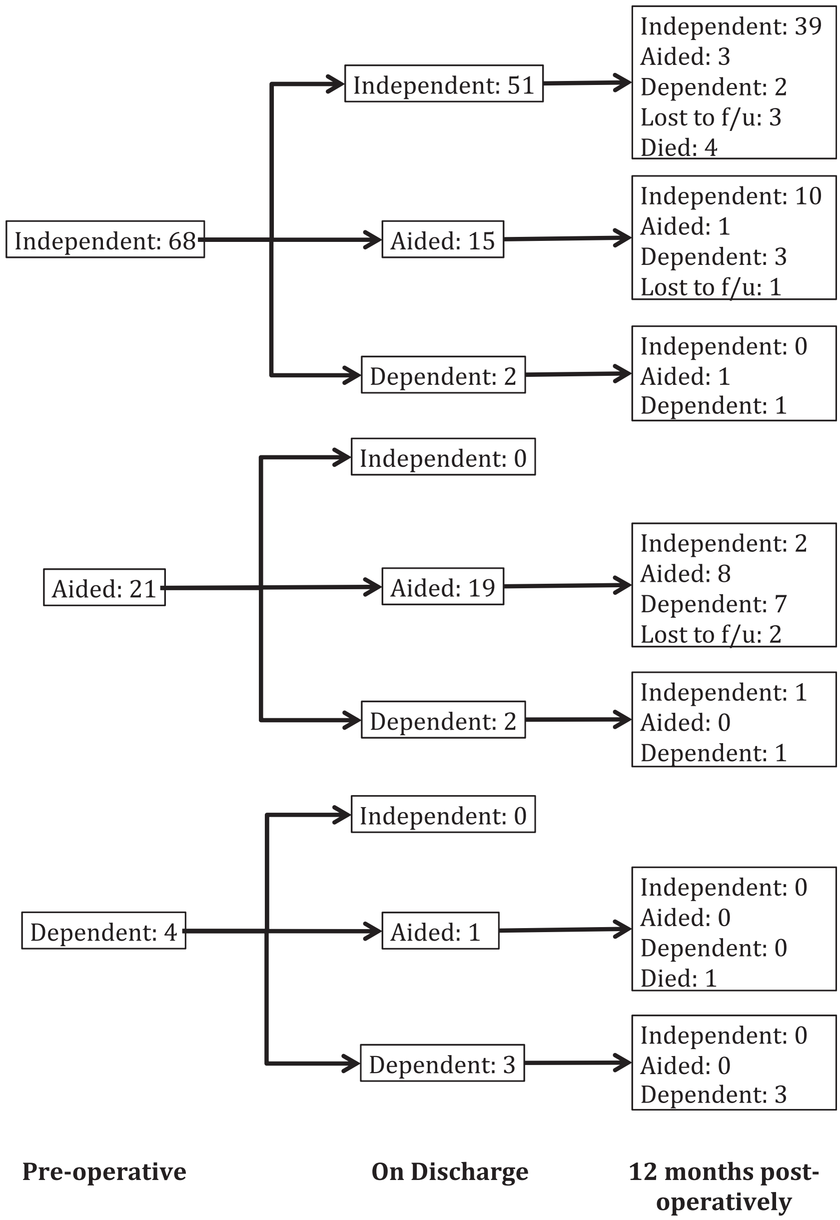

Fig. Change in mobility after lower limb bypass surgery (LLBS). *f/u,* Follow-up.

six patients who underwent redo LLBS were independently mobile before their initial operation. Three of these patients remained independent at the 1-year follow-up, one required the aid of a walking frame, one had amputation below the knee after repeated graft failure and so was dependent on a wheelchair, and one died of other causes. Eight patients were dependent at the 12-month follow-up despite patent grafts. Of these, three had contralateral amputations on admission and failed to resume using their prostheses after surgery, and one went on to have a below-knee amputation, despite a patent graft, for chronic pain at 11 months. This patient was thus dependent at the 12-month follow-up but subsequently went on to mobilize with a prosthesis. The remaining four patients became dependent as a result of comorbidities.

Factors predictive of postoperative mobility. Poor mobility on discharge was strongly associated with prolonged length of stay and predicted by poor preoperative mobility ($P < .001$). Men and current smokers were significantly more likely to leave the hospital independently mobile ($P = .04$ and $P = .05$, respectively), but the male cohort was also significantly younger (median age, 69 years vs 78 years for women; $P = .002$). Patients presenting as an emergency were less likely to be independently mobile on discharge, although this failed to reach statistical significance ($P = .10$). Further details are presented in Table III.

Table III. Comparison of preoperative and perioperative predictors of independent mobility at discharge using nonparametric assessment of significant differences

Predictor	*Independent on discharge*	*Not independent on discharge*	P
Age, median (range), years	71 (45-89)	72 (29-90)	.46[a]
Male sex, %	78	57	.04[b]
Emergency admission, %	37	55	.10[b]
Current smoker, %	47	26	.05[b]
Preoperative independence, %	100	40	<.001[b]
Below-knee distal target, %	73	86	.14[b]
Vein graft, %	65	71	.83[b]
Finnvasc <2, %	55	50	.68[b]
PREVENT III <4, %	59	57	1.0[b]
RCRI <1, %	53	38	.21[b]
CRAB, mean ± SD	6.7 ± 4.5	9.0 ± 4.4	<.001[a]
Tissue loss, %	54	62	.53[b]
Length of stay, median (range), days	8 (2-30)	15 (3-40)	<.001[a]

CRAB, Comprehensive Risk Assessment for Bypass; *PREVENT,* Edifoligide for the Prevention of Infrainguinal Vein Graft Failure; *RCRI,* Revised Cardiac Risk Index; *SD*, standard deviation.
[a]Mann-Whitney *U* test.
[b]Fisher exact test.

Table IV. Comparison of predictors of poor mobility at the 12-month follow-up with nonparametric assessment of significant differences

Predictor	*Independent at 12 months*	*Not independent at 12 months*	P
Age, median (range), years	70 (45-89)	73 (29-88)	.22[a]
Male sex, %	77	54	.04[b]
Emergency admission, %	44	46	1.0[b]
Current smoker, %	42	34	.51[b]
Preoperative independence, %	94	43	<.001[b]
Below-knee distal target, %	79	83	.79[b]
Vein graft, %	75	66	.47[b]
Finnvasc <2, %	58	49	.51[b]
PREVENT III <4, %	62	57	.82[b]
RCRI <1, %	54	40	.27[b]
CRAB, mean ± SD	7.2 ± 4.4	8.6 ± 5.0	.01[a]
Tissue loss	48	69	.08[b]
Length of stay, median (range), days	8 (2-30)	15 (3-40)	<.001[a]
Graft patent at 12 months, %	88	50	.002[b]

CRAB, Comprehensive Risk Assessment for Bypass; *PREVENT,* Edifoligide for the Prevention of Infrainguinal Vein Graft Failure; *RCRI,* Revised Cardiac Risk Index; *SD*, standard deviation.
[a]Mann-Whitney *U* test.
[b]Fisher exact test.

At the 12-month follow-up, poor mobility was again associated with premorbid mobility and prolonged hospital length of stay during the index admission ($P < .001$) as well as being associated with graft failure. Men were still more likely to be mobile, but the associations with smoking and urgency of operation had disappeared. Assessment using the PREVENT III, Finnvasc, and RCRI risk scoring models was not associated with poor mobility at any time point. In contrast, the CRAB score was associated with poor postoperative mobility at discharge ($P < .001$) and at the 12-month follow-up ($P = .01$). Further details are presented in Table IV.

DISCUSSION

Traditional markers of outcome for patients undergoing LLBS have tended to be concerned with mortality, morbidity, and graft patency.[15] These are obviously important, but over recent years, increasing weight has been placed on more patient-related and patient-reported outcomes.[5] These include pain, ulcer healing, residential status, and postoperative mobility. Patients with CLI are often elderly, have underlying mobility issues, and the nature of the surgery can be extensive, with associated limb-related complications that can hinder postoperative mobility. This study emphasizes the significance of LLBS with regards to postoperative mobility, with a large number of patients failing to achieve independent mobility in the immediate postoperative period. Indeed, the requirement of walking aids significantly increases hospital stay. Although there was some improvement over the postoperative period with regard to independent mobility at 1 year, the rate of wheelchair dependence in the first postoperative year increased fourfold. This clearly implies a significant additional burden on health care resources.

Women undergoing LLBS for CLI were significantly more likely to have poorer mobility at discharge and at the 12-month follow-up. This may be partly related to the women being significantly older than their male counterparts. Not surprisingly, graft failure at 1 year was associated with poor mobility at follow-up, although graft failure did not automatically lead to amputation.

One surprising finding was that patients who were still smoking on admission were more likely to be independently mobile on discharge, with this association not evident at 1 year. It is possible that the initial good mobility was driven by the desire to leave the ward for regular cigarette breaks, although we are not advocating continued smoking in this patient cohort.

These results are broadly in keeping with the findings of a recent large systematic review that identified 10 studies analyzing >3000 patients with CLI.[16] The authors found preoperative mobility predicted postoperative mobility and that wheelchair dependence increased from 9% in the preoperative population to 22% at follow-up. In addition, absent or limited tissue loss, younger age, and long-term graft patency predicted good mobility, whereas diabetes and female sex predicted poor mobility.

Infrainguinal LLBS is still a commonly performed procedure within the UK.[17] The results presented in our study represent real-world experience outside the context of clinical trials and are likely to reflect practice within other UK centers. The retrospective nature of the study is associated with obvious limitations, but we believe our data capture is sufficient to reach robust conclusions. The relatively small sample size of the study means that negative results should be interpreted with caution.

It is becoming increasingly evident that patient-related outcomes are becoming more relevant in daily practice. Chisci et al[18] have developed a patient-orientated scoring system for revascularization in CLI. Using this, they suggested that up to 60% of patients would benefit from revascularization and that a nonoperative approach, including palliation, could be indicated in patients with poor preoperative living status. This is partly borne out within our study, where no patient with dependency maintained long-term mobility. Indeed, eight patients were dependent at the 12-month follow-up despite patent grafts, highlighting the inadequacy of graft patency as a measure of outcome. Before confining such patients to primary amputation or palliation, however, in-depth studies are required to specifically identify patients who will not benefit from surgical revascularization, particularly in light of the technologic advances in endovascular treatments. The correlation of the CRAB score with postoperative mobility is promising in this regard because it represents a step toward improving our ability to predict which patients are likely to have poor functional outcomes, with reasonable predictive power at discharge. Predictive power in the longer-term was still not optimal, so although this may represent a useful tool to direct resources during the inpatient stay, it cannot be relied on as a guide for longer-term prognosis.

CONCLUSIONS

Our study demonstrates that mobility has significant effects on both initial length of stay and longer-term outcomes in patients with CLI treated with lower limb bypass surgery. The implications of this in terms of patient experience and health care burden make this is an important area for further work in a patient population that is only going to increase in size.

AUTHOR CONTRIBUTIONS

Conception and design: PC
Analysis and interpretation: GA, PC
Data collection: GA, AD, NZ, PH, MG, JB, KV, PC
Writing the article: GA, AD, PC
Critical revision of the article: GA, AD, NZ, PH, MG, JB, KV, PC
Final approval of the article: GA, AD, NZ, PH, MG, JB, KV, PC
Statistical analysis: GA
Obtained funding: GA
Overall responsibility: PC

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Supplementary Table I (online only). Summary of risk scores calculated

Scoring System	*Criteria*	*Scoring*
Finnvasc[11]	Diabetes Coronary artery disease Foot gangrene Urgent operation	Each scores 1 point
PREVENT III[12]	Dialysis dependence Tissue loss Age >75 years Hematocrit ≤0.3 Coronary heart disease	4 points 3 points 2 points 2 points 1 point
RCRI[13]	High risk surgery Ischemic heart disease Congestive cardiac failure Cerebrovascular disease Insulin-dependent diabetes mellitus Creatinine ≥177 μmol/L	Each scores 1 point
CRAB[10]	Age >75 years Prior amputation/revascularization Tissue loss Partial functional dependence Dialysis dependence Recent angina/MI Emergency operation Total functional dependence	3 points 3 points 3 points 3 points 4 points 4 points 6 points 6 points

CRAB, Comprehensive Risk Assessment for Bypass; *MI,* myocardial infarction; *PREVENT III*, Project of Ex-Vivo graft Engineering via Transfection III; *RCRI,* Revised Cardiac Risk Index.

Supplementary Table II (online only). Details of inflow and outflow vessels of grafts

	Proximal			*Distal*			
Anastomosis	*CFA*	*SFA/PFA*	*Pop*	*AK pop*	*BK pop*	*Tibioperoneal*	*Foot vein*
Grafts	86	4	3	20	43	29	1

AK, Above knee; *BK,* below knee; *CFA,* common femoral artery; *PFA,* profunda femoris artery; *SFA,* superficial femoral artery.

Supplementary Table III (online only). Conduit type used for bypass[a]

Conduit type	*No.*
Long saphenous vein	53
Spliced vein	15
Prosthetic with cuff	16
Prosthetic without cuff	8

[a]In one patient it was not possible to determine the conduit type due to missing medical notes.

Supplementary Table IV (online only). TransAtlantic Inter-Society Consensus (*TASC*) 2 classification of femoropopliteal lesions treated with lower limb bypass surgery (LLBS)

	TASC 2 class			
	A	*B*	*C*	*D*
Patients	0	10	32	51

Supplementary Table V (online only). Reason for treating critical limb ischemia (CLI) with lower limb bypass surgery (LLBS) rather than angioplasty

Indication for bypass	*No.*
Unsuitable for angioplasty (eg, flush SFA occlusion)	39
Failed angioplasty	15
Reoccluded lesion/ulcer still not healing after angioplasty	13
Upstream procedure requiring outflow	10
Redo bypass	6
Thrombosed SFA/popliteal aneurysm	4
Surgeon preference	6

SFA, Superficial femoral artery.